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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,095	02/28/2002	Balazs Sumegi	1060-0144P	8470

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,095

Applicant(s)

Sumegi Balazs

Examiner

Phyllis G. Spivack

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 7, and 10-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/446,064.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4</u> | 6) <input type="checkbox"/> Other: |

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A Preliminary Amendment filed May 21, 2003, is acknowledged. Claims 4, 5, 8 and 9 are canceled. New claims 11-19 are presented. Accordingly, claims 1-3, 6, 7 and 10-19 are presently under consideration.

The Response to the request for an election of species filed June 18, 2003, Paper No. 7, is further acknowledged. Applicant has elected O-(3-piperidino-2-hydroxy-1-propyl)-nicotinic amidoxime with traverse as a single hydroximic acid derivative.

The traversal is based on Applicant's view that no statements are advanced for the reasoning behind the requirement nor a case of a serious burden in searching all claims. Applicant argues there is no undue burden to the Examiner since a class of compounds is claimed.

Applicant's arguments have been given careful consideration but are not found persuasive. A plethora of compounds are encompassed in Applicant's definitions of a pharmaceutical composition comprising both a known active substance having antitumor activity that is a pyrimidine derivative and a compound of instant formula I. The search required for one composition, with one specific hydroximic acid derivative that does not have a heterocyclic moiety, along with fluorouracil, for example, would vary from another composition having a hydroximic acid derivative with a heterocycle. Distinctness of the methods and compositions is further evidenced by the different classification of compounds of formula I when R^1 and R^2 , together with the nitrogen atom to which they are attached, form a plethora of structures, and, the option wherein X and Y together form various ring structures. Moreover, as to the burden of the search, classification is merely one indication of the burdensome nature of the required search.

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The literature search of the large number of both possible pyrimidine derivatives and compounds of instant formula I claimed herein is not necessarily co-extensive and is a major factor in determining search burden. Clearly different issues exist and an election of a single, disclosed species of formula I is proper.

The subject matter presently under consideration are pharmaceutical compositions and methods of use comprising an antitumor pyrimidine derivative, as disclosed in the specification, and O-(3-piperidino-2-hydroxy-1-propyl)-nicotinic amidoxime, or a pharmaceutically acceptable acid addition salt thereof.

An Information Disclosure Statement filed February 28, 2002, Paper No. 4, is further acknowledged and has been reviewed.

Claims 1, 3, 6 and 11-18 are rejected under judicially created doctrine as being drawn to an improper Markush group. Lack of unity of invention has been found to exist since a common nucleus among the various derivatives of formula I is absent when a heterocyclic moiety is encompassed within the structure. A prior art references anticipating the claims under 35 U.S.C. 102 with respect to one species where the hydroximic acid derivative is BGP-15; for example, would not render the same claims obvious under U.S.C. 103 with respect to another species without heterocycles. Deletion of the non-elected subject matter would resolve the issue.

As Markush claims that lack unity of invention, claims 1, 3, 6 and 11-18 will be examined fully only with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

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Claims 1, 3, 6 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In the recitation within the definition of R^1 and R^2 together, "preferably" renders the claims indefinite. It is unclear whether or not a claim limitation is intended concerning the subject matter following the term "preferably".

Claims 1, 2 and 6 are rejected under 35 U.S.C. 112, both first and second paragraph, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the invention, and for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

The metes and bound of "pyrimidine derivative" cannot be precisely determined. Applicant fails to particularly point out the definition of pyrimidine derivatives having an antitumor effect. Numerous compounds that lack enablement and an adequate teaching as to how to prepare them are encompassed in the term "pyrimidine derivative". Undue experimentation would be required to embrace the scope of the claims. Applicant should recite those derivatives contemplated.

Claims 1-3, 6, 7 and 10-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Compound "L" and Fluorouracil, as disclosed in Table 6, pages 27-28, does not reasonably provide enablement for any pyrimidine derivative with any hydroximic derivative of instant formula I. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to prepare compositions and to practice methods for reducing side effects commensurate in scope with these claims. The specification does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to carry out the invention.

The elected species is free of the prior art.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

July 10, 2003

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**